

2  
Cont

21. (NEW) The method of Claim 17, wherein the immunological method is selected from the group consisting of a two-site radioimmunometric assay, an IRMA, and a sandwich ELISA.

---

#### REMARKS

The currently claimed invention comprises antibodies or fragments of antibodies that are capable of detecting active hPTH, as well as immunological methods of use of these antibodies and antibody fragments. The present invention is capable of detecting active hPTH as opposed to inactive hPTH. It is important in measuring the amount of hPTH to determine the health status of humans that one be certain that the hPTH being measured is active, having biological activity, and is not inactive hPTH that may be a metabolic by-product. Inactive hPTH does not provide accurate information about the active hormone status of the human. For example, hPTH is known to play an important role in the metabolism of calcium.

In the current response, Claims 3-5 have been cancelled without prejudice. Claims 7 through 21 have been added and are currently pending in this application. No new matter has been added. The specification has been amended to identify this application's priority relationship to a PCT application. Further, the Specification has been amended to provide sequence identification numbers for the sequences disclosed therein.

#### PRIORITY

The Examiner stated that the Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 371 because the first sentence of the Specification did not contain a specific reference to the prior application. Applicants have amended the Specification herein such that the first sentence states that this application was filed under 35 U.S.C. § 371 and claims priority from PCT/EP95/03757.

#### COMPLIANCE WITH SEQUENCE RULES

The Examiner stated that the application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821 – 1.825, because each disclosure of a sequence is not accompanied by the required reference to a relevant sequence identifier. Applicants have amended the Specification herein to provide the relevant sequence identifier numbers for each sequence in the Specification.

#### CLAIM OBJECTIONS

The Examiner objected to Claims 3-5 because the Claims depended from a canceled claim. Applicants have cancelled Claims 3-5 herein. Applicants therefore respectfully request that the objections to the claims be withdrawn.

#### REJECTIONS UNDER 35 U.S.C. §§ 101 AND 112, SECOND PARAGRAPH

The Examiner rejected Claims 3-5 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regards as their invention. Claim 5 was further rejected as improperly defining a process because the steps of the method were not set forth in the claim. Applicants have canceled Claims 3-5 herein, thereby making the rejection moot. Applicants therefore respectfully request that the rejections under 35 U.S.C. §§ 101 and 112, second paragraph, be withdrawn.

#### REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected Claims 3-5 under 35 U.S.C. § 112, first paragraph, stating that the Specification does not enable a person skilled in the art to make and/or use the invention commensurate in scope with the claims. Applicants have canceled Claims 3-5 herein, thereby making the rejection moot. Applicants therefore respectfully request that the rejection

under 35 U.S.C. § 112, first paragraph, be withdrawn.

Further, Applicants respectfully submit that the Specification is enabling of the scope of the now pending claims which are drawn to antibodies or fragments of antibodies and methods of using the same in binding assays. The Examiner stated that the Specification was enabling for antibodies raised against the disclosed peptides and for methods of detecting hPTH peptides comprising contacting a sample with the antibodies or fragments thereof and assaying for binding.

#### REJECTIONS UNDER 35 U.S.C. § 102

The Examiner has rejected Claims 3-5 under 35 U.S.C. § 102(b) as being anticipated by Nussbaum *et al.* (1982, Chemical Abstracts 96 (5), Abstract No. 29060) or Tampe *et al.* (1982, J. Immunoassay 13(1): 1-13). Applicants have canceled claims 3-5, thereby making the rejection moot. Applicants therefore respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn. The following remarks are directed to the novelty of the currently pending claims.

The Examiner stated that "Nussbaum *et al* teach an antibody which binds an hPTH epitope defined as hPTH (25-34)." Applicants respectfully submit that Nussbaum *et al* fail to teach antibodies and antibody fragments which selectively bind to active hPTH or antibodies and antibody fragments that are capable of binding to the N-terminus of hPTH. Without selectively binding to active hPTH or the N-terminus of hPTH, Nussbaum *et al* cannot specifically anticipate Applicants' currently claimed invention. Thus, Nussbaum *et al* fail to teach each element in the currently pending claims.

The Examiner stated that "Tampe *et al* teach antibodies which bind several hPTH epitopes including hPTH(24-30) and hPTH(12-19)." Applicant respectfully submit that Tampe *et al* fail to teach antibodies and antibody fragments which selectively bind to active hPTH or

antibodies and antibody fragments that are capable of binding to the N-terminus of hPTH. Without selectively binding to active hPTH or the N-terminus of hPTH, Tampe *et al* cannot specifically anticipate the Applicants' currently claimed invention. Thus, Tampe *et al* fail to teach each element in the currently pending claims.

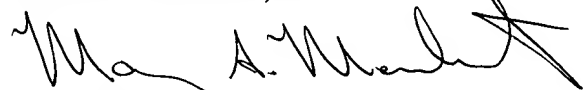
Because neither Nussbaum *et al.* nor Tampe *et al.* teach each element of the pending claims, Applicants respectfully submit that neither reference anticipates the currently pending claims.

#### CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the Office Action has been completely responded to and that the pending claims are now in condition for allowance. Such action is respectfully requested. If the Examiner believes any informalities remain in the application which may be corrected by Examiner's amendment, or if there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 818-3700 is respectfully solicited.

Respectfully submitted,

JONES & ASKEW, LLP



By: Mary Anthony Merchant, Ph.D.  
Reg. No. 39,771

191 Peachtree Street, N.E.  
37th Floor  
Atlanta, Georgia 30303-1769  
(404) 818-3700  
J&A Docket: 07826-0007